

CERVICAL CYTOLOGY SCREENING AND MANAGEMENT OF ABNORMAL CERVICAL CYTOLOGY

I. INTRODUCTION

The Maryland Department of Health and Mental Hygiene's Family Planning and Reproductive Health Program requires all delegate agencies to initiate cervical cytology screening protocols that are consistent with current national professional organization standards. Delegate agencies site Medical Directors must ensure providers follow guidelines issued by the American College of Obstetricians and Gynecologists (ACOG).

Most cervical cancer occurs in women who were either never screened or were inadequately screened. Estimates suggest that 50% of the women in whom cervical cancer is diagnosed never had cervical cytology testing, and another 10% have not been screened within the 5 years before diagnosis. Thus, approximately 60% of diagnoses of cervical cancer are a result of inadequate screening. Additional public health measures remain critical to improving access to screening for this group of women who are often uninsured or underinsured. Although rates of cervical cancer are on the decline in women born in the United States with access to screening, women who are immigrants to the United States, those lacking a regular source of health care, and the uninsured are at especially high risk. (1)

For the follow-up of abnormal cervical cytology results, the Family Planning and Reproductive Health Program requires that delegate agencies follow the American Society for Colposcopy and Cervical Pathology's (ASCCP) 2012 Updated Consensus Guidelines for the Management of Abnormal Cervical Cancer Screening Tests and Cancer Precursors. ASCCP Guidelines are referenced in this document and may be found at <http://www.asccp.org>.

II. CERVICAL CYTOLOGY SCREENING RECOMMENDATIONS

A. General screening recommendations:

1. Cervical cytology using either Liquid-Based Cytology or Conventional (slide) Pap Test (and high-risk HPV co-testing as appropriate) is the standard screening test for cervical cancer and precancerous cervical lesions.
2. Cervical cytology cancer screening should be initiated per age-specific recommendations (as outlined below). A woman may need other reproductive healthcare such as contraceptive initiation and STI screening at an earlier age. Cervical cytology is not a prerequisite to the provision of these services.
3. A pelvic exam (speculum and bimanual) should be performed at the same time as the Pap test and is only required every three to 5 years (unless medically indicated more frequently).
4. For Chlamydia STI screening and testing (when a pelvic exam is not indicated) CDC guidelines recommends the use of first-catch urine testing or vaginal self

- swab instead of a pelvic exam and endocervical sample, if available.
5. All recommendations for “HPV testing” refer to high-risk HPV testing (HR-HPV). Low-risk HPV testing has no utility and should not be done.
 - a. In select circumstances, “genotyping” of HPV (for strains 16/18 or 16 alone) may be useful for further triage after a diagnosis of a positive HR-HPV. See ASCCP guidelines for details.
- B. Age-based screening recommendations:
1. For the purpose of these guidelines an ADOLESCENT is defined as an individual 20 years of age or younger.
 2. Pelvic exams (speculum and bimanual) on females 13-20 years of age are no longer required unless medically indicated (i.e., symptoms or conditions related to sexually transmitted disease, vaginitis, abnormal vaginal bleeding, amenorrhea, pelvic pain, foreign body or pelvic mass).
 3. Screening for cervical cancer should begin at age 21.
 4. Adolescents must be able to obtain appropriate preventative health care, including, but not limited to, an assessment of health risks, counseling for pregnancy and sexually transmitted infection (STI) prevention, contraception, and treatment of STI's; even if they do not need a Pap smear.
 5. HPV vaccination should be encouraged for girls, adolescents, and young women aged 9-26.
 6. Adolescents and young women who have received the HPV vaccine should continue cervical cancer screening according to the current recommendations
 7. For women aged 20-39 years, the performance of a clinical breast examination is recommended every 1-3 years. A clinical breast examination should be performed annually for women aged 40 years and older
- C. Overview of Recommendations for Cervical Cancer Screening:
1. In November 2012, ACOG released a Practice Bulletin revising cervical cancer screening recommendations. This Practice Bulletin incorporates new screening recommendations from the American Cancer Society, ASCCP and the American Society for Clinical Pathology.
 2. Pap testing should not be deferred if vaginal discharge or signs and symptoms of vaginal infection are present.
 3. The ASCCP and ACOG guidelines, including recommendation for spacing of pap smears, are for women with normal immune status and who are at average risk for development of cervical cancer. Women at high risk for cervical neoplasia should be screened using alternate guidelines. These women include those with:
 - a. HIV
 - b. Immune compromise (eg: solid organ transplant clients)
 - c. DES exposure in-utero
 - d. History of cervical cancer

Cervical Cytology Screening Recommendations

Age to Begin	Screening Exam	Screening Interval
Age 21-29	Conventional Pap Test OR Liquid Based Cytology (LBC)	Every three years, unless an abnormality is detected
Age \geq 30- 65*	Conventional Pap Test only OR Liquid Based Cytology only OR Liquid Based Cytology with HR-HPV co-testing (preferred)	Every three years OR Every five years, unless an abnormality is detected. Frequency should be individualized using clinical judgment
Age > 65	No screening necessary	Only applies for immunocompetent women without a history of CIN 2-3, AIS, or cervical cancer within the last 20 years

* High-Risk Human Papillomavirus testing as an adjunct to cervical cytology testing may be used for cervical cancer screening in women 30 years of age or older. HR-HPV co-testing should not be performed for women <30 during routine screening. HR-HPV testing is still appropriate for clients aged 21-29 to triage ASCUS pap smear results. For abnormal results, follow-up guidelines may be found on <http://www.asccp.org>. HR-HPV testing is not a funded Title X family planning test. However, sites can opt to use their funds to pay for this test.

D. Contraindications for Pap Screening:

1. Visible cervical mass with bleeding
 - a. These women should be immediately referred for colposcopy / biopsy.

E. Conditions that may increase risk of inadequate sample:

1. Heavy menstrual bleeding. To improve quality of sample, the cervix can be lightly wiped with a cotton swab stick. The use of liquid-based cytology greatly decreases the risk of a specimen being obscured by blood.
2. Women less than 6-8 weeks post-partum (vaginal delivery) or 6-8 weeks post-abortion. If appropriate, post-partum/post-abortion pap smears should be conducted at 6 weeks post-partum/post-abortion, but if necessary, can be done earlier with the knowledge that inflammatory results are more common in a postpartum pap smear done at less than 6-8 weeks postpartum. Post partum status should not be a reason to delay follow-up of prior abnormal cervical cancer screening.

III. CLIENT INFORMATION/EDUCATION

- A. Regular cervical cancer screening (Pap test) is viewed as an important component of routine preventive care. Screening (via client history) and testing for sexually transmitted infections, if indicated, should occur at the annual visit even if cervical cancer screening is not done.
- B. Discuss the importance of cervical cancer screening which includes:
 - 1. Frequency of cervical cancer screening is based on recommendations from a nationally recognized professional organization, a woman's age and her Pap test history.
 - 2. Cervical cancer screening test is a Pap test. (Frequency of Pap testing is dependent on previous Pap test results and current medical status.)
 - 3. Possible need for testing for HPV or other STI's
- C. Discuss limitations of screening procedures
 - 1. Normal results on a screening exam do not necessarily indicate absence of disease.
 - 2. No screening test is 100% accurate; therefore, some cases of the disease may be unavoidably missed. Thus, regular follow-up is recommended even after normal screening results.
 - 3. Normal results never rule out the later development of the disease, which is why regular screening is so strongly recommended.
 - 4. The detection of an abnormality does not mean the abnormality is cancerous. Only some women with abnormal screening results will, after further evaluation, be diagnosed with disease.

IV. ADDITIONAL CONSIDERATIONS AND MANAGEMENT OF WOMEN WITH SPECIAL CONDITIONS

- A. Special Considerations:
 - 1. Women with a histologically-confirmed HSIL (CIN 2 or CIN 3) should receive evaluation and possible treatment, –and should continue cervical cancer screening on a regular basis, for 20 years following diagnosis or treatment of HSIL.
 - 2. Women who are HIV+, immunocompromised, or had *in utero* DES exposure – should have ANNUAL cervical cancer screening regardless of the testing method.
 - a. Women with HIV should be screened twice during the year after diagnosis (every six months), and then annually if screening cytology is negative.
 - 3. For clients with unsatisfactory cytology and HPV unknown (or untested), cytology should be repeated in 2-4 months. With unsatisfactory cytology where HPV is known to be positive, the client should receive a colposcopy.
 - 4. If pap results are normal, but no endocervical component is identified, recommendations are determined by client age.
 - a. Age 21-29 – continue routine screening (q 3 years)
 - b. Age ≥30 – HPV testing preferred
 - i. if HPV negative, continue routine screening (q 5 years)

- ii. if HPV positive, perform genotyping (follow guidelines if HPV 16/18 positive) or perform cytology with HPV testing in 1 year
 - iii. If HPV unknown, repeat cytology in 3 years
- 5. For women 30 years of age and older with HPV-positive but cytology-negative co-testing results, repeat co-testing at 1 year is acceptable. At the 1-year repeat co-test, if the HPV test result is positive or cytology is ASC-US or worse, colposcopy is recommended. If the 1-year repeat co-test result is HPV-negative and cytology negative, repeat co-testing in 3 years is recommended. Human papillomavirus genotyping is also acceptable. If the HPV 16 and HPV 18 test results are positive, colposcopy is recommended. If HPV 16 and HPV 18 test results are negative, repeat co-testing in 1 year is recommended. (3)
- 6. Women who have had a total hysterectomy (cervix removed) who are immunocompetent and who have not had a history of CIN 2 or CIN 3 should not receive further pap smears.
- 7. Pregnant women: per the ASCCP pregnant women are given special consideration. See guidelines for details at <http://www.asccp.org>.
 - a. ASCUS: manage as non-pregnant women; may defer colposcopy to 6 weeks postpartum
 - b. LSIL: Immediate colposcopy preferred; may defer until 6 weeks postpartum
 - c. HSIL or ASC-H: manage as non-pregnant women

For ALL pregnant women undergoing colposcopy: Endocervical curettage (ECC) is contraindicated, and biopsies should be performed only in select circumstances.
- 8. Invasive cancer is the only indication for treatment during pregnancy.
- B. Provision of Screening and Diagnostic Services for Family Planning Women with Abnormal Pap Tests
 - 1. Women <40 years of age seen in a delegate agency family planning clinic site who have an abnormal Pap test result requiring follow-up for the abnormality can be referred to the Maryland Breast and Cervical Cancer Diagnosis and Treatment Program for diagnostic and treatment services if they meet the program eligibility criteria. For more information about the program eligibility requirements visit the Breast and Cervical Cancer Diagnosis and Treatment (BCCDT) Program website at http://fha.maryland.gov/cancer/bccdt_home.cfm or call 410-767-6787 or 1-800-477-9774.
 - 2. HPV testing should be discussed and recommended to the client.

V. MANAGEMENT OF ABNORMAL CERVICAL CYTOLOGY RESULTS

- A. Follow-up Process for Abnormal Pap Test Results must be established:
 - 1. Delegate agencies must develop and implement a tracking system that will notify women of cervical screening results and follow-up diagnostic testing that is required.
 - 2. A method of contacting women without violating their confidentiality must be established at the first visit.
 - 3. All women with an abnormal pap must be notified within 2 weeks of obtaining

the Pap test.

4. If the pap results are HSIL, AGC, Squamous CIS, or AIS, a regular letter and a certified letter should be sent to the client.
5. Documentation must be maintained in the medical record of all phone calls and letters to clients.
6. Colposcopy should be completed within 90 days of performing the pap test, therefore, it is recommended that follow-up be initiated as quickly as possible.
7. High-Risk Type HPV testing should be used for follow-up of ASC-US pap to determine management for either referral for colposcopy or return to routine screening.

B. Clinical Management of Pap Testing Results

1. ABNORMAL pelvic examination (abnormal gross appearance of cervix), NORMAL Pap test
 - a. Notify the woman of the results of her pelvic examination and its potential implication(s). This information should include:
 - i. The nature of the suspected disease and differentiation between a cervical lesion or other pelvic abnormality (ovarian mass) and implications for coverage by BCCDTP, etc.
 - ii. Refer immediately for colposcopy with biopsy as indicated. Do not rely on cervical cytology results alone.
 - b. Notify the woman's primary provider (if any).
 - i. The physical exam findings and screening test results
 - ii. BCCDTP role/action taken
2. UNSATISFACTORY cervical cytology specimen
 - a. A pap smear is considered unsatisfactory if it does not have adequate squamous cellularity, is not preserved and/or fixated correctly, or if there are significant obscuring elements such as blood or inflammatory elements.
 - b. For clients with unsatisfactory cytology and HPV unknown (or untested), cytology should be repeated in 2-4 months.
 - c. If unsatisfactory cytology where HPV is known to be positive, the woman should receive repeat cytology testing in 2-4 months or undergo colposcopy.
 - d. Colposcopy is recommended for women with two consecutive unsatisfactory cytology test results (3).
3. NO ENDOCERVICAL COMPONENT: If pap results are normal, but no endocervical component is identified, recommendations are determined by client's age.
 - a. Age 21-29 – continue routine screening (q 3 years)
 - b. Age ≥30 – HPV testing preferred
 - i. if HPV negative, continue routine screening (q 5 years)
 - ii. if HPV positive, perform genotyping (follow guidelines if HPV 16/18 positive) or perform cytology with HPV testing in 1 year
 - iii. If HPV unknown, repeat cytology in 3 years
4. ABNORMAL cervical cytology report
 - a. Notify the woman of the results of the Pap test and its implications as soon as possible but within 6 weeks of receipt of abnormal findings, including:
 - i. Specifics regarding the results
 - ii. Clarification that many cervical lesions are not cancerous, but rather

- precancerous lesions which require follow-up. Many may spontaneously resolve and/or are treatable
- iii. The need for further testing for definitive diagnosis before treatment
- iv. Treatment options available, benefits and risks of each
- b. Refer/arrange for repeat Pap test and/or diagnostic work-up and treatment based on Pap test results. Please refer to algorithms via links below in section VI or to summary table APPENDIX 2.

VI. FOLLOW-UP OF ABNORMAL CYTOLOGY RESULTS

Summary Table of ACOG Recommendations included in APPENDIX 2

The website <http://www.asccp.org> contains algorithms for:

- A. Unsatisfactory cytology
- B. Normal cytology with absent cervical cytology
- C. Normal cytology with HPV positive test
- D. Management of ASCUS, LSIL, ASC-H, HSIL, AGC
- E. Management of CIN 1 after “lesser abnormalities”
- F. Management of CIN 1 after ASC-H / HSIL
- G. Management of CIN 2, 3
- H. Management of AIS
- I. Management of *young women* (21-24) with ASCUS, LSIL, ASC-H, HSIL
- J. Management of *young women* (21-24) with no lesion or CIN 1; CIN 2, 3
- K. Management of *pregnant women* with LSIL

VII. ADDITIONAL INFORMATION

Indications for referral to a qualified colposcopist:

- A. Women requiring treatment for CIN2/3 (if using the ACS screening recommendations).
- B. Pregnant women with HSIL cytology.
- C. Women with a significant cervical lesion in which immediate biopsy may be indicated.
- D. Women desiring fertility who, after excisional treatment, have recurrent or persistent cervical dysplasia.
- E. Women who have had two “unsatisfactory for evaluation” tests 2-4 months apart.
- F. Women with AGC (Abnormal Glandular Cells) or AIS (Adenocarcinoma in situ) on cytology. Management follows the algorithm found at <http://www.asccp.org>. Summary list of algorithms included in APPENDIX 1.
- G. Women with any gynecologic cancer should be referred to a Gynecologic Oncologist.

REFERENCE

1. American College of Obstetricians and Gynecologists--Obstetrics & Gynecology, Practice Bulletin #131 "Screening for Cervical Cancer". November, 2012.
2. Massad LS, et al., "2012 Updated Consensus Guidelines for the Management of Abnormal Cervical Cancer Screening Tests and Cancer Precursors", J Lower Genital Tract Dis 17(5), S1-S27, 2013.

3. American College of Obstetricians and Gynecologists—Obstetrics & Gynecology, Practice Bulletin #140 "Management of Abnormal Cervical Cancer Screening Test Results and Cervical Cancer Precursors". December, 2013.
4. Guidelines for Women's Health Care: A Resource Manual, 4th edition. American College of Obstetricians and Gynecologists, 2014.
5. American College of Obstetricians and Gynecologists – Frequently Asked Questions: Gynecology, #187. "Abnormal Cervical Cancer Screening Test Results". January, 2016.

APPENDIX 1 LISTING OF ASCCP ALGORITHMS

To access algorithms, please go to: <http://www.asccp.org>.

1. Unsatisfactory Cytology
2. Cytology NILM but EC/TZ Absent / Insufficient
3. Management of Women ≥ 30 who are Cytology Negative but HPV Positive
4. Management of Women with ASCUS on Cytology
5. Management of Women Ages 21-24 with ASCUS or LSIL
6. Management of Women with LSIL
7. Management of Pregnant Women with LSIL
8. Management of Women with ASC-H
9. Management of Women Ages 21-24 with ASC-H and HSIL
10. Management of Women with HSIL
11. Initial Workup of Women with AGC
12. Subsequent Management of Women with AGC
13. Management of Women with No Lesion or Biopsy-confirmed CIN 1 Preceded by "Lesser Abnormalities"
14. Management of Women with No Lesion or Biopsy-confirmed CIN 1 Preceded by ASC-H or HSIL Cytology
15. Management of Women Ages 21-24 with No Lesion or Biopsy-confirmed CIN 1
16. Management of Women with Biopsy-confirmed CIN 2, 3
17. Management of Young Women with Biopsy-confirmed CIN 2, 3 in Special Circumstances
18. Management of AIS during a Diagnostic Excisional Procedure
19. Interim Guidance for Managing Reports using LAST Histopathology Diagnoses

APPENDIX 2

SUMMARY RECOMMENDATIONS

CERVICAL CYTOLOGY RESULTS FOLLOW-UP

This table shows the recommended follow-up for women who have had no prior abnormal cervical cancer screening test results. Follow-up is different when an abnormal cervical cancer screening test result occurs in a woman who has had a prior abnormal result.

	<i>Ages 21–24</i>	<i>Ages 25–29</i>	<i>Ages 30 and Older</i>	
			<i>HPV Negative</i>	<i>HPV Positive</i>
Normal Pap test results	Routine screening: Pap test every 3 years	Routine screening: Pap test every 3 years	Routine screening: Preferred— Co-testing* every 5 years Acceptable— Pap test alone every 3 years	Acceptable— Co-testing* in 12 months Acceptable— HPV typing†
ASC-US	Preferred— Repeat Pap test in 12 months Acceptable— Reflex HPV test‡	Preferred— Reflex HPV test‡ Acceptable— Repeat Pap test in 12 months	Repeat co-testing* in 3 years	Colposcopy
LSIL	Repeat Pap test in 12 months	Colposcopy	Preferred— Repeat Pap test in 12 months Acceptable— Colposcopy	Colposcopy
ASC-H	Colposcopy	Colposcopy	Colposcopy	Colposcopy
HSIL	Colposcopy	Immediate excisional treatment or colposcopy	Immediate excisional treatment or colposcopy	Immediate excisional treatment or colposcopy
AGC	AGC has several subcategories. The type of follow-up tests that are recommended depend on the AGC subcategory. Tests performed for follow-up include colposcopy, endocervical sampling, and endometrial sampling.			

Abbreviations: ASC-H = atypical squamous cells, cannot rule out HSIL; ASC-US = atypical squamous cells of undetermined significance; AGC = atypical glandular cells; HPV = human papillomavirus; HSIL = high-grade squamous intraepithelial lesion; LSIL = low-grade squamous intraepithelial lesion.

*Co-testing: Combined Pap test and HPV test

†HPV typing: A test for the presence of HPV type 16 and HPV type 18

‡Reflex HPV test: A test for the presence of high-risk HPV types using the sample used for a Pap test

SOURCE: American College of Obstetricians and Gynecologists – Frequently Asked Questions: Gynecology, #187. “Abnormal Cervical Cancer Screening Test Results”. January, 2016.